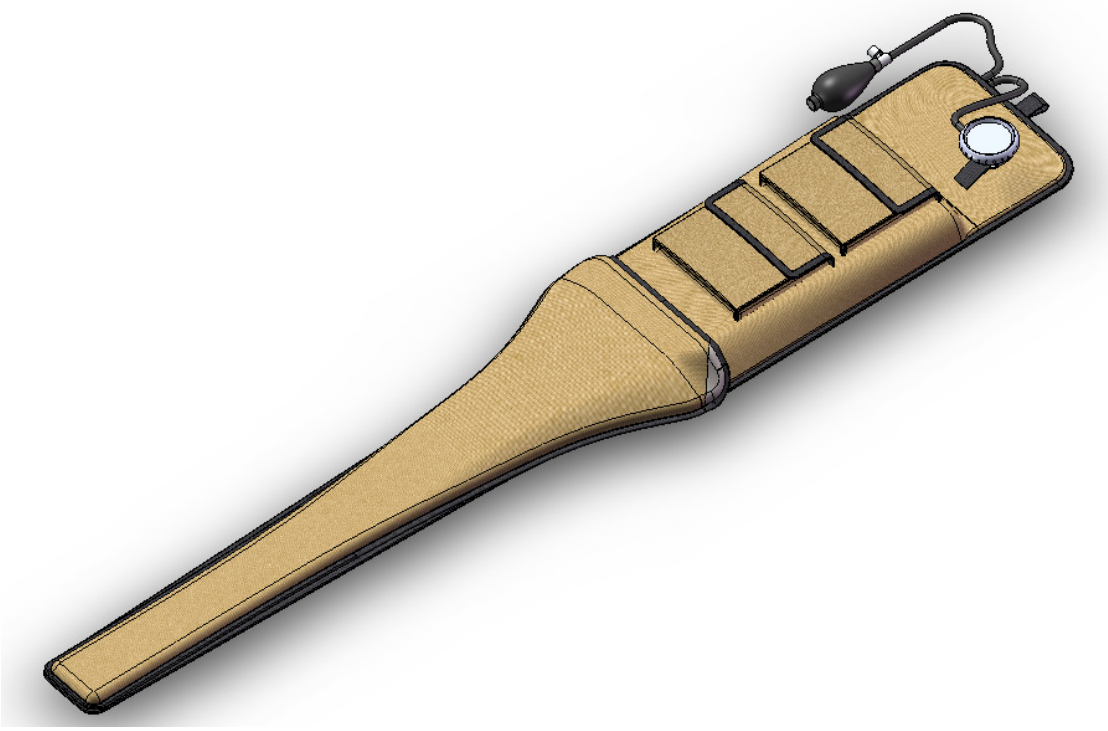
INFU Plus

Type 0612A

-Temperature insulation cover and pressurizer for IV liquid



User Manual
including;
-Service manual

INFU Plus is manufactured by Medical Rescue Equipment (MRE) Holding AS

INFU Plus bears the CE marking and complies with the provisions of the Medical Device Directive 93/42/EEC
and harmonized standards of the directive.

The Device is also compliant with the Swedish LVFS 2003:11, the Norwegian FOR 2005-12-15 nr.1690 and applicable requirements from SS-EN ISO 13718-1 Air, water and difficult terrain ambulances –Part 1: Medical device interface requirements for the continuity of patient care.

Additionally the device complies to all applicable parts of the standards listed in Appendix II, Applicable standards.

This manual reflects INFU Plus, type 0612A.

Revision 01 of manual May 09.

MRE Holding AS

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2 General

2.1 Classification

INFU Plus is a medical device classified as shown in Table 1:

Table 1: Classification

	Classification
EU/ CE-mark	Class I
USA/ FDA	Class I

IP44

The device is IP-classed to IP44. This means that the device is classed to class 4 both for dust/ sand tightness and for water tightness. The device is protected against solid particles of a diameter of 1mm and proof against splashing water.

2.2 Label with technical information

On the inside of INFU Plus upper pocket lid, a label is placed with technical information of the device (see Figure 1).

Figure 1: Double-sided label with technical information for INFU Plus.

2.3 Intension of device

The single major cause of death in potentially salvageable battlefield casualties is hemorrhage, and the greatest opportunity for reducing mortality and morbidity of battlefield casualties involves fluid resuscitation and treatment of hypovolemia (an abnormal decrease in the volume of blood plasma). In the past, it has been difficult to prevent hemorrhaging on the battlefield because there was no way to keep infusion liquids in a temperature controlled environment over an extended time.

INFU Plus offers improved IV liquid logistics in field possibility to:
1) Store and protect pre-heated IV bags during transport in the field to the location of accident. The protection includes coverage and thermo-isolation
2) Provide the possibility to pressurize the IV bag, thus providing accurate transport through the infusion set, without the use of a traditional infusion stand.

3 Meaning of symbols

Existing symbols on the INFU Plus unit or in User manual.

Symbol	Meaning
CE	CE mark. Indicates that the product complies with the Medical Device Directive 93/42/EEC.
	“Warning!!”, “Caution!” or “Note.”. This symbol indicates need for extra observance. Consult user manual for further information.
IPN_1N_2	IP-class. N_1 indicates the dust/sand-tightness (proofness for ingression of dust/ sand) of the device, N_2 indicates the waterproofness (proofness for the ingresseion of water/ humidity) of the device,
LOT	Lot/ batch number. A number indicating a certain mength of devices manufactured under the same conditions/ same occation (manufactured under one work day, sterilized in same set, or similar).
	Manufacturing date. Indicates the date of manufacture for the unit.

4 Instructions before use

Make sure to read the User manual before operating the INFU Plus!

Make sure to follow procedure in *Use procedure* (see below) for every use of INFU Plus.

The device is only intended to be operated by personnel with medical education!

Service for device is only to be performed by qualified service personnel, according to descriptions in the appended service manual.

4.1.1 Check flow:

Always check manually that there is flow in INFU Plus during infusion!

4.1.2 Room-tempered device:

Use room-tempered INFU Plus if available.
Store INFU Plus for 10 minutes in room temperature before mounting IV bag in cover if device has been stored in temperature “lower than” < +10°C or “higher than” > +50°C.

4.1.3 Warm environment:

Never use INFU Plus and IV bag that has been mounted for more than 1 hour in an environment warmer than +42°C after being pre-heated!!

4.2 Restrictions

4.2.1 High target temperature:

Warning!! Too high target temperatures might be dangerous to the patient! Temperatures over body-temperature endeavours the patient-safety since it risks coagulation and thrombosis or hyperthermia. Never mount an IV bag with dangerously high temperature in INFU Plus cover.

4.3 Handling of IV liquid bags

4.3.1 Restrictions for IV liquid vessel and volume:

-Intended IV liquid bags are soft plastic bags with maximum 1000 ml IV liquid.
-INFU Plus is designed to hold and pressurise one liquid bag at the time.

4.3.2 Restrictions for procedure/ handling of IV liquid bags:

Caution!

-Do not use IV liquid that is blurry or non-transparent!
-Only use new, sealed IV liquid bags (nor earlier used on patients)!

Besides these restrictions, follow standard procedure for handling of IV liquid bags and instructions from supplier.

4.4 Other accessories and consumables

Accessories and consumables to use with INFU Plus except for IV bags are infusion sets and cannulas.

All accessories and consumables shall be handled according to instructions from the manufacturer of each component.

4.4.1 Infusion set

The infusion sets used shall include spike and clamp, but **without drip chamber**. The length of the tube shall be between 650 and 900 mm, preferably 750 mm.

4.4.2 Cannulas

Standard cannulas with Luer lock couplings can be used. The cannula inner diameter controls the rate of the infusion. Therefore, this factor must be decided by MD personnel for each particular situation.

4.4.3 Cannula diameter

The diameter of the cannula has a big impact on the **infusion rate** with INFU Plus. In Figure 2 below, a comparison is made between INFU Plus flow-rate (with no patient) and flow-rate from a traditional infusion stand set-up. In both cases a “pink cannula” (BD Venflon, gauge 20) was used.

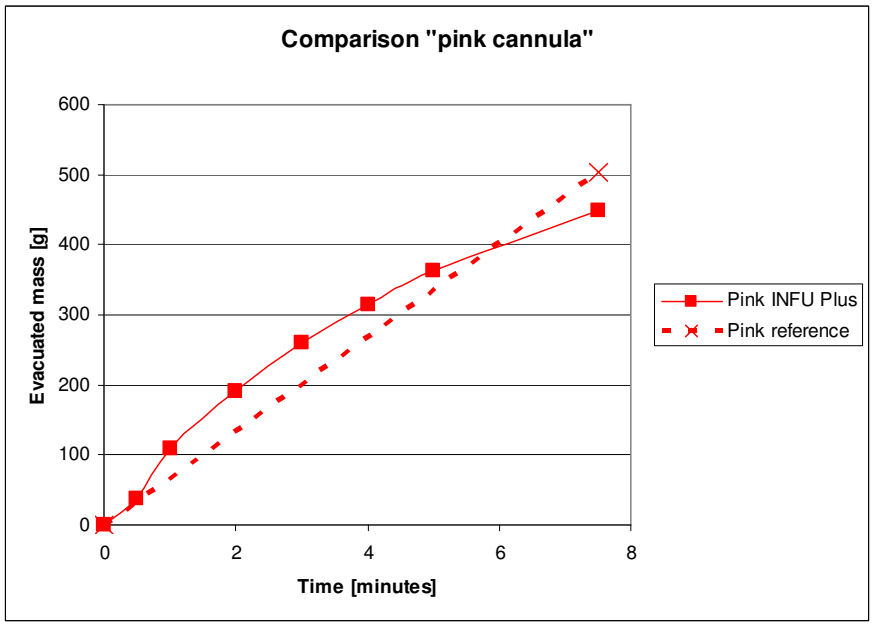


Figure 2: Comparison for the first 7.5 minutes between INFU Plus flow-rate and traditional infusion stand. In both cases "pink cannula" was used (BD Venflon).

Figure 3 compares INFU Plus flow-rate for three different outlet diameters (pink/gauge 20; yellow/gauge 30, and no cannula). The INFU Plus flow-rate is typically 60-70 ml/min during the first minutes. The nominal flow-rate of the chosen cannula is 67 ml/min (measured from traditional infusion stand).

Without repeated pressurization the INFU Plus flow-rate typically drops after some minutes (see Figure 3).

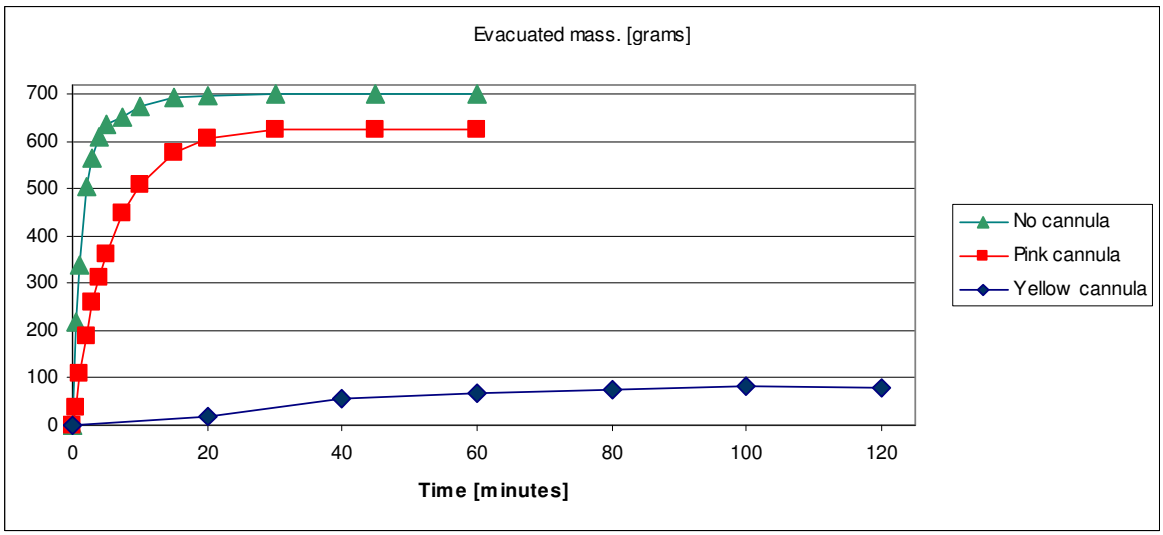


Figure 3: INFU Plus performance for three different outlet diameters; No cannula, pink cannula =gauge 20, yellow cannula = gauge 30.

4.5 Environmental requirements/ Operating specifications

4.5.1 Environment

The manufacturer only takes responsibility for the function of the device when used in situations which fulfil the following conditions:

Ambient temperature:	-45°C – +70°C, (-49°F - +158°F)
Relative humidity (in combination with temperature):	5°C, 20%RH -3°C, 95%. (41°F, 20 % RH - 37°F, 95%) 50°C, 5-95% RH. (122°F, 5-95% RH)
Atmospheric pressure:	Normal atmospheric pressure on ground, anywhere on earth.

Whenever not in direct use, store manometer and hand pump in safety pocket (see § 5.1 and Figure 4).

4.5.2 Storage/ transport

Whenever storing or transporting INFU Plus, the manometer and hand pump shall be mounted inside its safety pocket (see Figure 4)!

Ambient temperature:	-45°C – +70°C, (-49°F - +158°F)
Relative humidity (in combination with temperature):	No
Atmospheric pressure:	Normal atmospheric pressure on ground, anywhere on earth.

5 Use Procedure

5.1 The product and interface

The product is intended to replace an infusion stand with pressurisation by inflatable bladder. The cover has thermo-properties that maintains an acceptable temperature on tempered IV liquid.

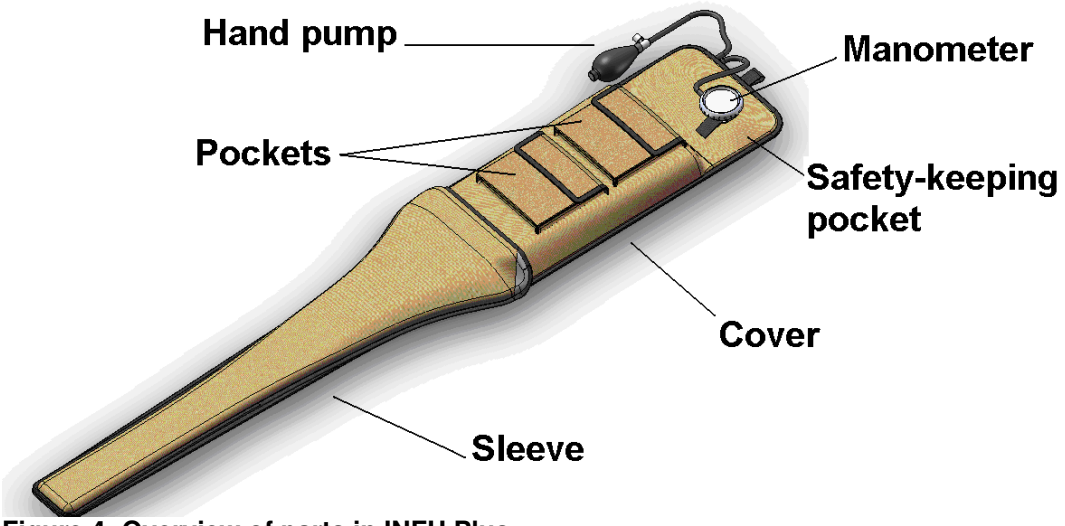


Figure 4: Overview of parts in INFU Plus.

5.1.1 Hand pump

There is a hand pump with a check valve. This pump is used to manually inflate the device when IV bag is mounted.
-Note! If temperature is below zero the hand pump becomes stiffer and difficult to pressurise. Manually warm up hand pump and make a new try to pressurise device.
Whenever not in use, store in safety pocket.

5.1.2 Manometer

The manometer shows the pressurisation of the device. The infusion pressure shall be 100-200 mmHg (as shown by the red areas).
Whenever not in use, store in safety pocket.

5.1.3 Cuff

The cuff (placed inside a pocket) is used to protect temperature of the cannula when mounted on patient. The cuff also protects from blood soil!

5.1.4 Straps

There are two straps for INFU Plus. The long strap, see
Figure 5, is a shoulder strap used to carry an INFU Plus. The short strap is used to carry two devices at once. When the short strap is fastened in the end of two devices, one person can carry on INFU Plus on one's back and one in front of him/ her.

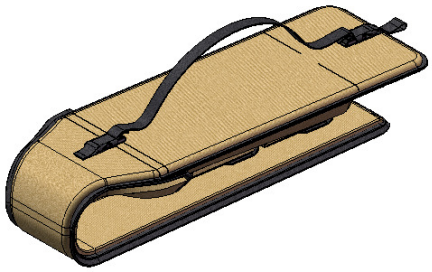
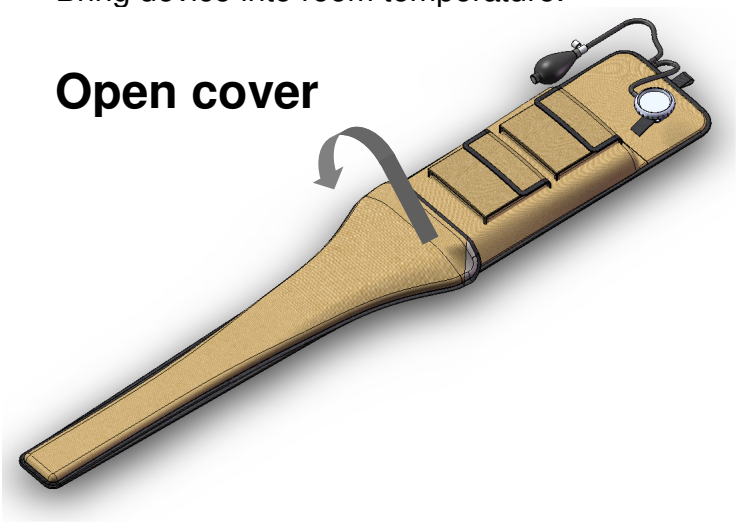


Figure 5: Folded device with long shoulder strap.

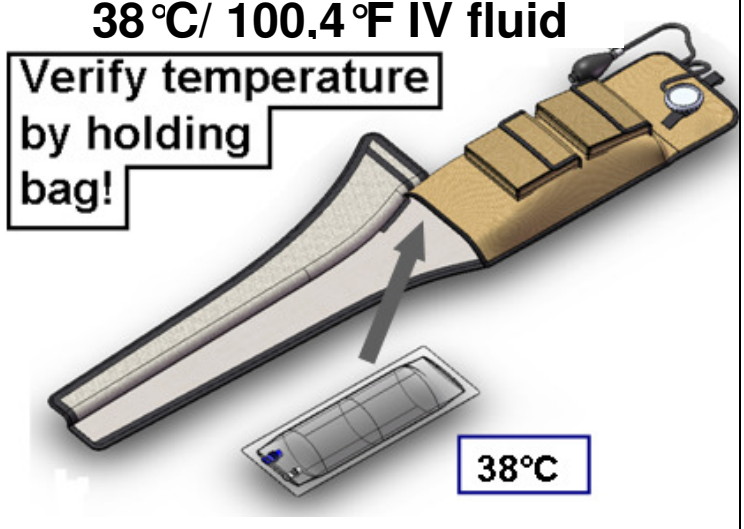
5.2 Infusion with INFU Plus

1.

Bring device into room temperature.

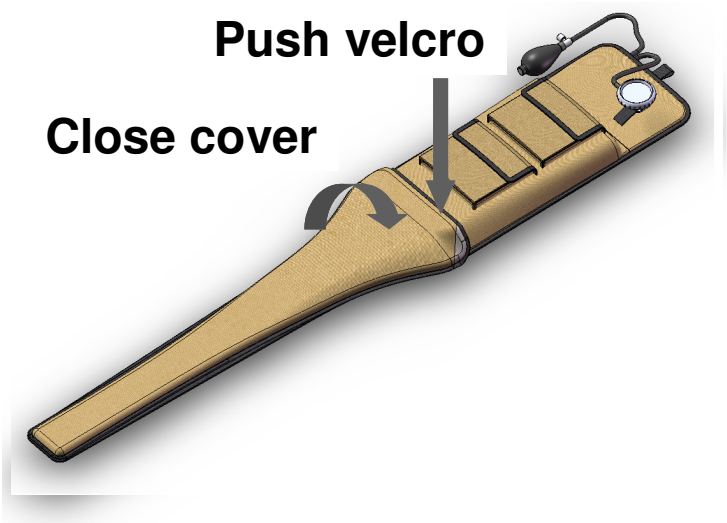


2.

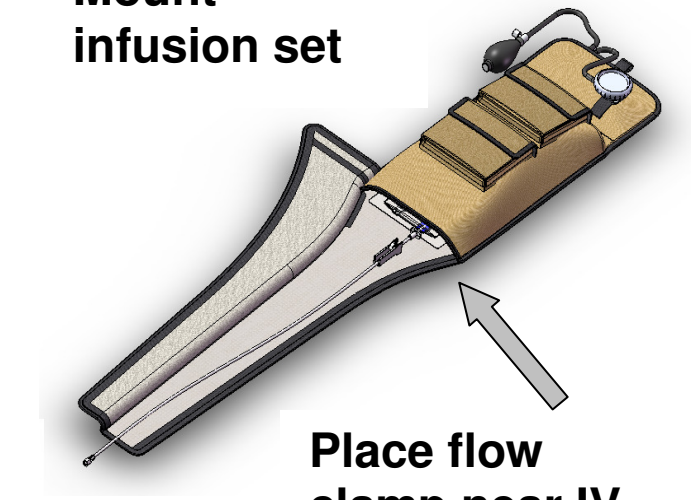


3.

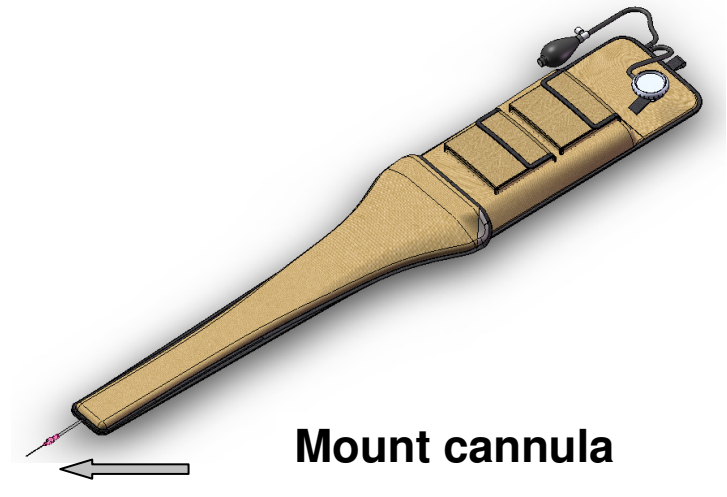
Control that cover is firmly closed with Velcro.



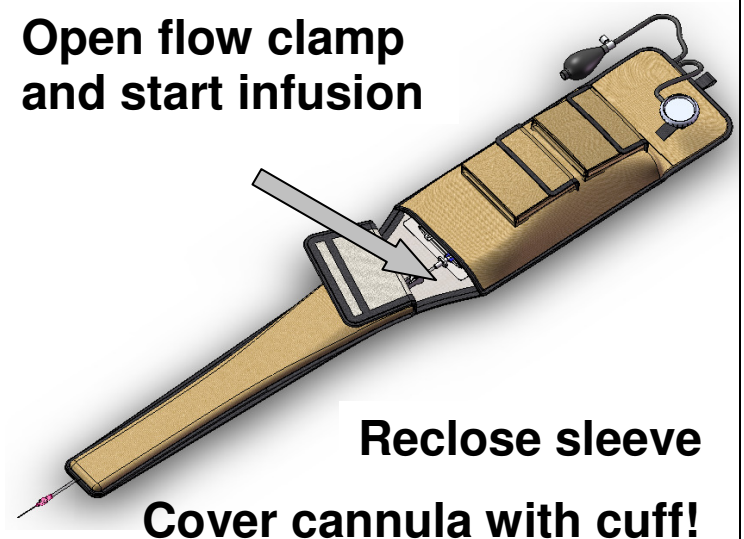
4.



5. When at use-site;



6.



5.3 Rush infusion with INFU Plus

If a rush infusion is necessary. Use normal procedure, but re-pressurise INFU Plus every 2nd minute to 200 mmHg.

6 Cleaning, Maintenance and contamination

6.1 Maintenance

For INFU Plus to function fully the maintenance procedure included in the *service manual*, (Appendix II), should be performed at least **once a year**.

For every use:

Ocular inspection of the device in order to exclude any visible damages.
After use, check that device is clean and otherwise clean it (see § 6.2 Cleaning and § 6.3 Contamination).

6.2 Cleaning

INFU Plus is *not* intended for washing. The device can be cleaned from dirt with a moist cloth or sponge and typical cleaning detergents available for households (e.g. alcohol, dishwasher detergent, soap etc.) A disinfectant cleaning detergent is preferable if available.

Do not soak the device.

6.3 Contamination

If there is danger of contamination of the device (blood soil or leakage of IV bag for example), be sure to cover injured skin with INFU Plus cuff or other medical cover.

INFU Plus does not guarantee protection from blood infections.

If there is blood soil on device or cuff that could give hazards of contamination, the device or cuff shall be replaced.

7 Service and Spare parts

All service procedures shall be performed by professional technical service personnel.

For further information, see the attached *Service manual*.

8 Manufacturers contact info

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3901 Porsgrunn, Norway

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Fax: +47 35515014
E-mail: info@mre-holding.com
Homepage: www.mre-holding.com

9 Product data sheet

Company name:	Medical Rescue Equipment (MRE) Holding AS
Product name:	INFU Plus
Model designation:	0612A (Military IV thermos, A = first release version)
Description:	Fully insulated cover and sleeve with high pressure system all in one, for infusion bags of maximum 1000 ml. Maintains temperature of pre-heated or pre-cooled infusion liquids. The INFU Plus is intended to be used mainly in emergency situations like military fields, accidents and in catastrophes. Integrated with the insulated cover there is an inflatable bladder with a manometer, for high pressure as a substitute for an infusion stand.
Size:	Length: about 1250 mm. Width: about 200 mm. Height: about 60 mm (IV bag excluded). Weight: about 1-1.2 kg
Drive:	Manually driven infusion with rubber bladder and high-pressure system.

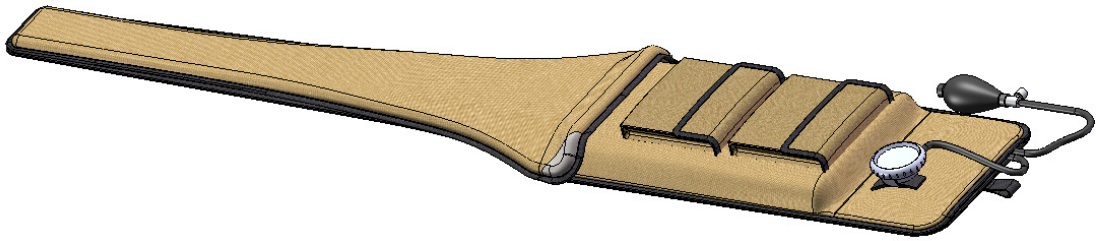

Figure 6: A perspective view of whole product.

10 Definitions/ glossary

Flow clamp	A clamp used to stop the flow of liquid.
Rush infusion	Infusion performed as fast as possible.

Appendix I

Applicable standards

Title	Standard	Regarding
Directives		
Medical Device Directive	93-42-EEC 2007	Design
Units of Measure Directive	80-181-EEC	Labelling
Provisions for medical equipment "Läkemedelsverkets föreskrifter om medicintekniska produkter"/ "Forskrift om medisinsk utstyr"	 LVFS 2003:11/ FOR 2005-12-15 nr 1690:	Design, manufacturing
Medical device GMP (Good Manufacturing Practice)	FDA QSR 21CFR, Part 820:1996	
Quality Regulation		
Medical devices - Quality management systems - Requirements regulatory purposes	ISO 13485:2003	Quality
Quality management systems -regulatory	ISO 9001:2008	Quality
Application of Risk Management to Medical Devices	SS-EN ISO 14971:2007	hazard analysis, design, content of info supplied by maufacturer
Analysis techniques for system reliability – FMEA	IEC 60812:2006	Design
Labelling		
Information Supplied by the Manufacturer of Medical Devices	SS-EN 1041:1998	Properties of information supplied by manufacturer
Graphical symbols for use in the labelling of medical devices	SS-EN 980:2008	Labelling
Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied -Part 1 General requirements	ISO 15223:2007	Labelling
Labeling regulations	21 CFR Part 801	Labelling
Labeling regulations	21 CFR Part 820, Subpart K	
Data elements and interchange formats – Information interchange -- Representation of dates and times	ISO 8601:2004	Labelling
Mechanical and environmental		
Air water and difficult terrain ambulances	ISO 13718-1	Design
Degrees of protection provided by enclosures (IP code) +Amendment 1 +Corrigendum 2	SS-EN 60529:1992, +A1:2000, + Cor 2:2007	
US Army Medical Materiel Agency (USAMMA) Protocol for Climatic and environmental engineering considerations.	(no standard. Test methods found in MIL STD 810F)	
Department of Defence Test method standard for environmental engineering considerations.	MIL-STD-810F*	

Additional standards controlling specific material properties for fabrics etc, have been used in design and are documented in the technical documentation of the product..

INFU Plus

Type 0612A

-Temperature insulation cover for IV liquids

Service Manual

E.1.1 Requirements and Information

E.1.1.1 Requirements

Service on this device is only to be performed by personnel with fitting education (technical service personnel).

E.1.1.2 Information

All important information is included in the user manual.

E.4.1 Delivery control

E.4.1.1 Delivery control

a) Do an ocular inspection of the device.

b) Ensure that cuff, straps and infusion sets are included with the product.

c) Pressurise device to 200 mmHg and check the performance according to § E.5.1.1 , test g) air leakage.

d) Test manometer according to § E.5.1.1 , test h) manometer.

E.5.1 Maintenance, cleaning and contamination

E.5.1.1 Maintenance

For INFU Plus to function fully the following procedure should be performed at least **once a year**;

e) Cleaning:
INFU Plus is **not** intended for washing. Be careful not to soak the device. The device can be cleaned from dirt with a moist cloth or sponge and typical cleaning detergents available for households (e.g. alcohol, dishwasher detergent, soap etc.) A disinfectant cleaning detergent is preferable if available.

f) Ocular inspection:

-**Velcro:**

Check velcro on device. If Velcro is used-up, throw away device and order new. (Broken velcro will decrease thermo-performance.)

-**Cover:**

Check that cover and sleeve on device are intact. Check that strap attachments are intact. Pull straps to ensure function.

-**Cracks:**

See that rubber parts (hand pump and tubes) do not show signs of cracking. If cracking is found, order spare part and exchange. Tubes can not be changed since they are integrated with bladder inside cover. In case of cracking on outer end of tube, cut loose the cracked part and re-attach manometer or hand pump to the remaining tube. (Consider that the tube has to be long enough to reach safety-pocket.) The metal collar must be firmly closed around the tube to ensure that there is no leakage. Manufacturer do not take responsibility for collar fastened by customer.

-Couplings:

Check manually that couplings for manometer, hand pump and vent are firmly attached and air tight.

g) Air leakage:

-Mount room tempered IV bag in device. Pressurise with 200mmHg. (Make sure that air vent is closed.)
-After 5 minutes check manometer pressure. If the pressure is above 150 mmHg the INFU Plus is working properly.
-Otherwise; if manometer pressure is between 100 and 150 mmHg, perform test again. If still not above 150 mmHg the second time – perform test h).
-Otherwise; if manometer pressure is below 100 mmHg, check function according to h) and follow recommendations.

h) Manometer, hand pump and vent function:

-Pressurise device to 200 mmHg and observe manometer response. Manometer needle shall move smoothly. (Make sure that air vent is closed.)
-Decompress INFU Plus. Needle shall return to zero-value.
-If needle function does not correspond to description, the manometer shall be replaced.
-If device, including manometer leaks above the limit value stated in c.), detach manometer, hand pump and vent from device and attach manometer directly to hand pump and vent (with an air-tight, flexible tube in the correct size). Pressurise manometer (with closed vent).
-If leakage remains, detach vent and attach manometer directly to pump (with tube). Manually pressurise to 200 mmHg.

If manometer leaks above the limit value stated in c), the manometer shall be replaced. If the vent or the hand pump seems to be the problem they should be replaced. Otherwise replace INFU Plus with a new unit.

E.5.1.2 Cleaning

INFU Plus is *not* intended for washing. The device can be cleaned from dirt with a moist cloth or sponge and typical cleaning detergents available for households (e.g. alcohol, dishwasher detergent, soap etc.) A disinfectant cleaning detergent is preferable if available.

Do not soak the device.

E.5.1.3 Contamination

If there is danger of contamination of the device (blood soil or leakage of IV bag for example), be sure to cover injured skin with INFU Plus cuff or other medical cover.

INFU Plus does not guarantee protection from blood infections.

If there is blood soil on the device or cuff that could give hazards of contamination, the device/ cuff shall be replaced.

E.6.1 Troubleshooting

E.6.1.1 Inadequate pressurisation of device

If pressurising of bladder does not work;

-Note! If temperature is below zero the hand pump becomes stiffer and difficult to pressurise. Manually warm up hand pump and make a new try to pressurise device.
-Note! Pressurisation of bladder requires a large number of pumps with the hand pump.
-Check that air vent is closed.
-Check the tubes and hand pump for cracks in material. If cracks are found, order new spare part.
-Manually check that all couplings are air tight (tube to manometer, vent to hand pump and tube to vent.
-If all couplings are visually air tight, perform check according to f) (where applicable) and g) from § 5.1.1.
-If tests according to f) and g) are still ok, test device according to h)

E.6.1.2 Unsatisfying manometer response

If the manometer does not work satisfactory, perform test h) manometer from § 5.1.1 Maintenance.

E.6.1.3 Service support

If problems still remain, please contact manufacturing company MRE Holding AS.

E.7.1 Recycling instructions

E.7.1.2 Recycling of INFU Plus

When INFU Plus is used up, remount hand pump, vent and manometer. Recycle metal parts and rubber parts as recommended by authorities for these certain materials.

E.8.1 Service and Spare parts

E.8.1.1 Service

For any national warranty (applicable on consumer products) to apply, the recommended delivery control and service routines must be performed by professional technical personnel.

If device does not work satisfying, perform troubleshooting according to E.6.1 Troubleshooting.

Spare parts possible to order are hand pump, vent, metal collars for tube and manometer.

E.9.1 Contact information to Manufacturer

E.9.1.1 Manufacturer contact information

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Postboks 186
3901 Porsgrunn, Norway
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